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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,725	08/01/2003	David E. Wolf	205-007US2	2807
27791	7590	01/29/2007	EXAMINER	
ALLISON JOHNSON, P.A. LAKE CALHOUN EXECUTIVE CENTER 3033 EXCELSIOR BLVD., SUITE 467 MINNEAPOLIS, MN 55416			SHIBUYA, MARK LANCE	
		ART UNIT	PAPER NUMBER	
		1639		
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
31 DAYS	01/29/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/632,725	WOLF ET AL.	
	<b>Examiner</b> Mark L. Shibuya, Ph.D.	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 October 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-66, 68 and 70-138 is/are pending in the application.
- 4a) Of the above claim(s) 1-58, 70, 72-117 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 59, 60, 130 and 138 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

Art Unit: 1639

**DETAILED ACTION**

1. Claims 1-66, 68, 70-138 are pending. Claims 67 and 69 are newly canceled.

Claims 118-138 are newly added.

2. Applicant, in the reply filed on 4/21/2006, in response to the elected the species of "pathogen" from the genus of "pathogen components", particularly as was claimed in independent claim 60 and newly canceled claim 67. The Requirement for

Restriction/Election, mailed 3/21/2006, in part stated:

This application contains claims directed to the following patentably distinct species: A pathogen component comprising a bacterium, virus, pathogen, pathogen fragment, pathogen nucleic acid, pathogen protein, pathogen carbohydrate, combinations thereof (specify), pathogen spore, pathogen toxin, metabolic product of pathogen, combinations thereof (specify). The species are independent or distinct because the different pathogen components have different molecular structures that result in different properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 60, 65-69 are generic.

The Requirement for Restriction/Election at para. 13.

Former dependent claims 67 and 69, newly canceled, and as subject to a requirement for election of species, stated:

67. The method of claim 60, wherein said pathogen component is selected from the group consisting of pathogen, pathogen fragment, pathogen nucleic acid, pathogen protein, pathogen carbohydrate, and combinations thereof.

Art Unit: 1639

69. The method of claim 60, wherein said pathogen component is a pathogen and said probe is capable of binding to a pathogen.

Claims, entered 8/1/2003. Thus the claims of the elected invention were drawn to a generic "pathogen component" and the elected species thereof was "pathogen".

Newly amended independent claim 60 now states:

60. (Currently Amended) A method of assaying for the presence of a pathogen component in a sample, said method comprising: exciting said [a] sample with radiation, said sample comprising at least one probe capable of binding a predetermined pathogen component, and at least one fluorescent tag; measuring the fluorescence from a subvolume of said excited sample; analyzing the fluctuations of said fluorescence that are due to the diffusion or flow of said pathogen, when present, through said subvolume; and determining the presence or absence of said pathogen component.

Claims, entered 10/23/2006.

The examiner respectfully submits that applicant's amendment to the claims, entered 10/23/2006, in effect, has changed the elected species of pathogen into a genus, thereby rendering moot the election of the species in the reply filed on 4/21/2006. See also, amended claims 65, 66 and 67, which now state:

65. (Currently Amended) The method of claim 60, wherein said pathogen component comprises a bacterium.

66. (Currently Amended) The method of claim 60, wherein said pathogen component comprises a virus.

67. (Cancelled)

68. (Currently Amended) The method of claim 60, wherein said pathogen component is selected from the group consisting of comprises a pathogen, spore, pathogen toxin, metabolic product of pathogen, and combinations thereof.

69. (Cancelled)

Claims, entered 10/23/2006.

The examiner respectfully submits that applicant's amendments to the claims, entered 10/23/2006, has effectively canceled the elected species of pathogen. However, in the interests of compact prosecution, the examiner respectfully submits that the following new requirement for election of species, is proper in view of applicant's amendments to the claims.

***Election of Species***

3. This application contains claims directed to the following patentably distinct species: Applicant must elect a species of pathogen. The species are independent or distinct because different pathogens have materially different structures, functions and effects. It is noted that in the method of the instant invention, dimension is a limitation, as in the subvolume through which the "pathogen" travels. Furthermore, in applicant's reply, entered 10/23/2006, to the previous Office action, mailed 7/21/2006, applicant traverses the cited prior art reference of Rigler et al., by in part arguing "[a] molecule is not a pathogen. A pathogen is an organism. In addition, a pathogen is an agent that causes a disease state." Reply at p. 25. Therefore, the examiner respectfully submits that applicant's arguments may be considered to show that the various species of pathogen are not obvious variants of each other, in the context of the claimed invention.

Art Unit: 1639

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 59, 60, 130, 138 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya, Ph.D. whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Shibuya, Ph.D.  
Primary Examiner  
Art Unit 1639